

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ALEXION PHARMACEUTICALS, INC. :
352 Knotter Drive :
Cheshire, CT 06410 :

Plaintiff

v.

HON. JON W. DUDAS
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office

Office of General Counsel
United States Patent and Trademark Office :
P.O. Box 15667 :
Arlington, VA 22215 :
Madison Building East, Rm. 10B20 :
600 Dulany Street :
Alexandria, VA 22314 :

Defendant.

Case: 1:08-cv-02225
Assigned To : Roberts, Richard W.
Assign. Date : 12/23/2008
Description: Adm. Agency Review

COMPLAINT

Plaintiff Alexion Pharmaceuticals, Inc., for its complaint against the Honorable
Jon W. Dudas, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent Nos. 7,393,648 ("the '648 patent"); 7,396,917 ("the '917 patent"); 7,399,594 ("the '594 patent"); 7,408,041 ("the '041 patent"); 7,414,111 ("the '111 patent"); 7,427,665 ("the '665 patent"); and 7,435,412 ("the '412 patent"). Plaintiff Alexion Pharmaceuticals, Inc. seeks correction of patent term adjustment for these seven patents pursuant to the Administrative Procedure Act and 35 U.S.C. § 154(b)(4)(A).

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

PARTIES

3. Plaintiff Alexion Pharmaceuticals, Inc., (“Alexion”) is a Delaware corporation having a principal place of business at 352 Knotter Drive, Cheshire, Connecticut 06410.

4. Defendant Jon W. Dudas is the Under Secretary of Commerce of Intellectual Property and Director of the United States Patent and Trademark Office (“USPTO”), acting in his official capacity. The Director is the head of the USPTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

JURISDICTION AND VENUE

5. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

6. Venue is proper in this judicial district under 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Fed. R. Civ. P. 6(a)(3).

BACKGROUND FACTS APPLICABLE TO ALL COUNTS

8. Plaintiff Alexion is the assignee of the '648, '917, '594, '041, '111, '665, and '412 patents, as evidenced by assignment documents recorded at the USPTO. The entire right, title, and interest to the '648, '917, '594, '041, '111, '665, and '412 patents, including the right to sue and recover for past infringement thereof, is assigned to and is owned by Alexion. Alexion is therefore the real party in interest in this case.

9. 35 U.S.C. § 154(b) relates to the adjustment of patent term. Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.”

10. In calculating the patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the USPTO under 35 U.S.C. § 154(b)(1), as limited by any overlapping periods of delay by the USPTO as specified under 35 U.S.C. § 154(b)(2)(A), any disclaimer of patent term by the applicant under § 154(b)(2)(B), and any delay attributable to the applicant under § 154(b)(2)(C).

11. The errors in the USPTO’s patent term adjustment calculations are detailed in a recent order from the U.S. District Court for the District of Columbia in an action entitled *Wyeth v. Dudas*, No. 07-1492, 2008 U.S. Dist. LEXIS 76063 (D.D.C. Sept. 30, 2008). In *Wyeth*, the Court granted summary judgment against the USPTO, holding that the USPTO’s patent term adjustment calculation methodology was erroneous as a matter of law and inconsistent with 35 U.S.C. § 154.

12. 35 U.S.C. § 154(b)(4)(A) provides that “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

FIRST COUNT: U.S. PATENT NO. 7,393,648

13. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

14. Russell Rother and Dayang Wu are the inventors of U.S. Patent Application No. 10/453,698 (“the ’698 application”), entitled “Hybrid Antibodies.” The ’698 application was filed on June 3, 2003, and issued as the ’648 patent on July 1, 2008. On March 26, 2007, the applicants filed with the USPTO a request for continued examination (“the RCE”) of the ’698 application. The ’648 patent is attached as Exhibit A.

15. When the USPTO issued the ’648 patent on July 1, 2008, it erroneously calculated the entitled patent term adjustment for the ’648 patent as 462 days. Had the USPTO calculated the entitled patent term adjustment properly, the ’648 patent would be entitled to at least 758 days of patent term adjustment.

16. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). See 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO’s calculation of patent term adjustment for Plaintiff’s ’648 patent.

17. The patent term adjustment for the ’648 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the ’648 patent, is 462 days. (See Ex. A at 1). The determination of the 462-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the ’698 application to the date the patent issued (“B delay”), not including the period of time following Plaintiff’s request for

continued examination (*i.e.*, not including the period of time between the March 26, 2007 filing of the RCE, and the July 1, 2008 grant of the patent). The number of the days in the period from June 3, 2006 (three years after the filing date of the '698 application) until March 26, 2007 (the day the RCE was filed) is 296 days. Therefore, the correct patent term adjustment for the '648 patent, including both the 462-day period determined by the USPTO and this 296-day adjustment under 35 U.S.C. § 154(b)(1), is at least 758 days.

18. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '648 patent of a period of 538 days, which is the number of days attributable to USPTO examination delay ("A delay").

19. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '648 patent of a period of 296 days, which is the number of days the issue date of the '648 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

20. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." For the '648 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

21. Thus, the total period of USPTO delay is 834 days, which is the sum of the period of A delay (538 days) and the period of B delay (296 days).

22. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 76 days as determined by the USPTO.

23. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 758 days, which is the difference between the total period of USPTO delay (834 days) and the period of applicant delay (76 days).

24. The Defendant's imposition of only 462 days of patent term adjustment for the '648 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

SECOND COUNT: U.S. PATENT NO. 7,396,917

25. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

26. Katherine S. Bowdish, Shana Frederickson, and Mark Renshaw are the inventors of U.S. Patent Application No. 10/307,724 ("the '724 application"), entitled "Rationally Designed Antibodies." The '724 application was filed on December 2, 2002, and issued as the '917 patent on July 8, 2008. On July 31, 2006, the applicants filed with the USPTO an RCE of the '724 application. The '917 patent is attached as Exhibit B.

27. When the USPTO issued the '917 patent on July 8, 2008, it erroneously calculated the entitled patent term adjustment for the '917 patent as 413 days. Had the USPTO calculated the entitled patent term adjustment properly, the '917 patent would be entitled to at least 654 days of patent term adjustment.

28. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the

prior *Wyeth* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '917 patent.

29. The patent term adjustment for the '917 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '917 patent, is 413 days. (*See* Ex. B at 1). The determination of the 413-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the '724 application to the date the patent issued ("B delay"), not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the July 31, 2006 filing of the RCE, and the July 8, 2008 grant of the patent). The number of the days in the period from December 2, 2005 (three years after the filing date of the '724 application) until July 31, 2006 (the day the RCE was filed) is 241 days. Therefore, the correct patent term adjustment for the '917 patent, including both the 413-day period determined by the USPTO and this 241-day adjustment under 35 U.S.C. § 154(b)(1), is at least 654 days.

30. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '917 patent of a period of 575 days, which is the number of days attributable to USPTO examination delay ("A delay").

31. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '917 patent of a period of 241 days, which is the number of days the issue date of the '917 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

32. Section 35 U.S.C. § 154(b)(2)(A) states that “to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” For the ’917 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

33. Thus, the total period of USPTO delay is 816 days, which is the sum of the period of A delay (575 days) and the period of B delay (241 days).

34. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 162 days as determined by the USPTO.

35. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 654 days, which is the difference between the total period of USPTO delay (816 days) and the period of applicant delay (162 days).

36. The Defendant’s imposition of only 413 days of patent term adjustment for the ’917 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

THIRD COUNT: U.S. PATENT NO. 7,399,594

37. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

38. Russell Rother and Dayang Wu are the inventors of U.S. Patent Application No. 10/308,817 (“the ’817 application”), entitled “Hybrid Antibodies.” The ’817 application was filed on December 3, 2002, and issued as the ’594 patent on July 15,

2008. On March 26, 2007, the applicants filed with the USPTO an RCE of the '817 application. The '594 patent is attached as Exhibit C.

39. When the USPTO issued the '594 patent on July 15, 2008, it erroneously calculated the entitled patent term adjustment for the '594 patent as 512 days. Had the USPTO calculated the entitled patent term adjustment properly, the '594 patent would be entitled to at least 990 days of patent term adjustment.

40. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '594 patent.

41. The patent term adjustment for the '594 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '594 patent, is 512 days. (*See* Ex. C at 1). The determination of the 512-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the '817 application to the date the patent issued ("B delay"), not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the March 26, 2007 filing of the RCE, and the July 15, 2008 grant of the patent). The number of the days in the period from December 3, 2005 (three years after the filing date of the '817 application) until March 26, 2007 (the day the RCE was filed) is 478 days. Therefore, the correct patent term adjustment for the '594 patent, including both the 512-day period

determined by the USPTO and this 478-day adjustment under 35 U.S.C. § 154(b)(1), is at least 990 days.

42. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '594 patent of a period of 645 days, which is the number of days attributable to USPTO examination delay ("A delay").

43. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '594 patent of a period of 478 days, which is the number of days the issue date of the '594 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

44. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." For the '594 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

45. Thus, the total period of USPTO delay is 1123 days, which is the sum of the period of A delay (645 days) and the period of B delay (478 days).

46. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 133 days as determined by the USPTO.

47. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 990 days, which is the difference between the total period of USPTO delay (1123 days) and the period of applicant delay (133 days).

48. The Defendant's imposition of only 512 days of patent term adjustment for the '594 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

FOURTH COUNT: U.S. PATENT NO. 7,408,041

49. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

50. Katherine S. Bowdish, John McWhirter, Anke Kretz-Rommel, and Toshiaki Maruyama are the inventors of U.S. Patent Application No. 10/996,316 ("the '316 application"), entitled "Polypeptides and Antibodies Derived from Chronic Lymphocytic Leukemia Cells and Uses Thereof." The '316 application was filed on November 23, 2004, and issued as the '041 patent on August 5, 2008. On January 10, 2008, the applicants filed with the USPTO an RCE of the '316 application. The '041 patent is attached as Exhibit D.

51. When the USPTO issued the '041 patent on August 5, 2008, it erroneously calculated the entitled patent term adjustment for the '041 patent as 258 days. Had the USPTO calculated the entitled patent term adjustment properly, the '041 patent would be entitled to at least 306 days of patent term adjustment.

52. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '041 patent.

53. The patent term adjustment for the '041 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '041 patent, is 258 days. (*See* Ex. D at 1). The determination of the 258-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the '316 application to the date the patent issued ("B delay"), not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the January 10, 2008 filing of the RCE, and the August 5, 2008 grant of the patent). The number of the days in the period from November 23, 2007 (three years after the filing date of the '316 application) until January 10, 2008 (the day the RCE was filed) is 48 days. Therefore, the correct patent term adjustment for the '041 patent, including both the 258-day period determined by the USPTO and this 48-day adjustment under 35 U.S.C. § 154(b)(1), is at least 306 days.

54. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '041 patent of a period of 394 days, which is the number of days attributable to USPTO examination delay ("A delay").

55. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '041 patent of a period of 48 days, which is the number of days the issue date of the '041 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

56. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not

exceed the actual number of days the issuance of the patent was delayed.” For the ’041 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

57. Thus, the total period of USPTO delay is 442 days, which is the sum of the period of A delay (394 days) and the period of B delay (48 days).

58. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 136 days as determined by the USPTO.

59. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 306 days, which is the difference between the total period of USPTO delay (442 days) and the period of applicant delay (136 days).

60. The Defendant’s imposition of only 258 days of patent term adjustment for the ’041 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

FIFTH COUNT: U.S. PATENT NO. 7,414,111

61. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

62. Toshiaki Maruyama, Katherine S. Bowdish, Shana Frederickson, and Mark Renshaw are the inventors of U.S. Patent Application No. 10/737,252 (“the ’252 application”), entitled “Engineered Templates and Their Use in Single Primer Amplification.” The ’252 application was filed on December 15, 2003, and issued as the ’111 patent on August 19, 2008. On November 1, 2007, the applicants filed with the USPTO an RCE of the ’252 application. The ’111 patent is attached as Exhibit E.

63. When the USPTO issued the '111 patent on August 19, 2008, it erroneously calculated the entitled patent term adjustment for the '111 patent as 549 days. Had the USPTO calculated the entitled patent term adjustment properly, the '111 patent would be entitled to at least 870 days of patent term adjustment.

64. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '111 patent.

65. The patent term adjustment for the '111 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '111 patent, is 549 days. (*See* Ex. E at 1). The determination of the 549-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for the time from three years after the filing date of the '252 application to the date the patent issued ("B delay"), not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the November 1, 2007 filing of the RCE, and the August 19, 2008 grant of the patent). The number of the days in the period from December 15, 2006 (three years after the filing date of the '252 application) until November 1, 2007 (the day the RCE was filed) is 321 days. Therefore, the correct patent term adjustment for the '111 patent, including both the 549-day period determined by the USPTO and this 321-day adjustment under 35 U.S.C. § 154(b)(1), is at least 870 days.

66. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '111 patent of a period of 613 days, which is the number of days attributable to USPTO examination delay ("A delay").

67. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '111 patent of a period of 321 days, which is the number of days the issue date of the '111 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

68. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." For the '111 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

69. Thus, the total period of USPTO delay is 934 days, which is the sum of the period of A delay (613 days) and the period of B delay (321 days).

70. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 64 days as determined by the USPTO.

71. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 870 days, which is the difference between the total period of USPTO delay (934 days) and the period of applicant delay (64 days).

72. The Defendant's imposition of only 549 days of patent term adjustment for the '111 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the

language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

SIXTH COUNT: U.S. PATENT NO. 7,427,665

73. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

74. Katherine S. Bowdish and John McWhirter are the inventors of U.S. Patent Application No. 10/433,207 (“the ’207 application”), entitled “Chronic Lymphocytic Leukemia Cell Line.” The ’207 application is entitled to a date under 35 U.S.C. § 371(c)(1), (2), and (4) (“a § 371 date”) of May 30, 2003. The ’207 application issued as the ’665 patent on September 23, 2008. On August 6, 2007, the applicants filed with the USPTO an RCE of the ’207 application. The ’665 patent is attached as Exhibit F.

75. When the USPTO issued the ’665 patent on September 23, 2008, it erroneously calculated the entitled patent term adjustment for the ’665 patent as 379 days. Had the USPTO calculated the entitled patent term adjustment properly, the ’665 patent would be entitled to at least 812 days of patent term adjustment.

76. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO’s calculation of patent term adjustment for Plaintiff’s ’665 patent.

77. The patent term adjustment for the ’665 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the ’665 patent, is 379 days. (*See* Ex. F at 1). The determination of the 379-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(B), for

the time from three years after the § 371 date of the '207 application to the date the patent issued ("B delay"), not including the period of time following Plaintiff's request for continued examination (*i.e.*, not including the period of time between the August 6, 2007 filing of the RCE, and the September 23, 2008 grant of the patent). Pursuant to 37 C.F.R. § 1.702(b), an application's § 371 date is used in place of a filing date for purposes of calculating B delay. The number of the days in the period from May 30, 2006 (three years after the § 371 date of the '207 application) until August 6, 2007 (the day the RCE was filed) is 433 days. Therefore, the correct patent term adjustment for the '665 patent, including both the 379-day period determined by the USPTO and this 433-day adjustment under 35 U.S.C. § 154(b)(1), is at least 812 days.

78. Under 35 U.S.C. § 154(b)(1)(A), and according to the USPTO, the Plaintiff is entitled to an adjustment of the term of the '665 patent of a period of 607 days, which is the number of days attributable to USPTO examination delay ("A delay").

79. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '665 patent of a period of 433 days, which is the number of days the issue date of the '665 patent exceeds three years from the filing date of the application, not including the period of time following Plaintiff's request for continued examination ("B delay").

80. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." For the '665 patent, there is no overlap between the periods of A and B delay. Therefore, there is no period of overlap to be excluded from the patent term adjustment calculation.

81. Thus, the total period of USPTO delay is 1040 days, which is the sum of the period of A delay (607 days) and the period of B delay (433 days).

82. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 228 days as determined by the USPTO.

83. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 812 days, which is the difference between the total period of USPTO delay (1040 days) and the period of applicant delay (228 days).

84. The Defendant's imposition of only 379 days of patent term adjustment for the '665 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

SEVENTH COUNT: U.S. PATENT NO. 7,435,412

85. The allegations of paragraphs 1-12 are incorporated in this count as if fully set forth.

86. Katherine S. Bowdish and John McWhirter are the inventors of U.S. Patent Application No. 10/379,151 ("the '151 application"), entitled "Chronic Lymphocytic Leukemia Cell Line." The '151 application was filed on March 4, 2003, and issued as the '412 patent on October 14, 2008. The '412 patent is attached as Exhibit G.

87. When the USPTO issued the '412 patent on October 14, 2008, it erroneously calculated the entitled patent term adjustment for the '412 patent as 343 days. Had the USPTO calculated the entitled patent term adjustment properly, the '412 patent would be entitled to at least 1012 days of patent term adjustment.

88. This Court, in *Wyeth*, issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). *See* 2008 U.S. Dist. LEXIS 76063, at *10. The correct patent term adjustment methodology identified in the prior *Wyeth* action governs the USPTO's calculation of patent term adjustment for Plaintiff's '412 patent.

89. The patent term adjustment for the '412 patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '412 patent, is 343 days. (*See* Ex. G at 1). The determination of the 343-day patent term adjustment is in error, in that it fails to include an adjustment, as required by 35 U.S.C. § 154(b)(1)(A), for the 692 days attributable to USPTO delay in prosecuting the '151 application ("A delay"). Therefore, the correct patent term adjustment for the '412 patent, including the proper adjustment under 35 U.S.C. § 154(b)(1)(A) of 692 days, is at least 1012 days.

90. Under 35 U.S.C. § 154(b)(1)(A), the Plaintiff is entitled to an adjustment of the term of the '412 patent of a period of 692 days, which is the number of days attributable to USPTO examination delay ("A delay"). Here, the USPTO exceeded the 14 month limit (as set forth by 35 U.S.C. § 154(b)(1)(A)(i)) to issue a first office action as to the '151 application by 692 days.

91. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '412 patent of a period of 955 days, which is the number of days the issue date of the '412 patent exceeds three years from the filing date of the application ("B delay").

92. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent that periods of [A and B delay] overlap, the period of any adjustment granted under this subsection shall not

exceed the actual number of days the issuance of the patent was delayed.” In the case of the ’412 patent, there are 23 days of overlap between the periods of A and B delay. Therefore, 23 days of overlap must be excluded from the patent term adjustment calculation.

93. Thus, the total period of USPTO delay is 1624 days, which is the sum of the period of A delay (692 days) and the period of B delay (955 days), less the period of overlap between A and B delay (23 days).

94. Pursuant to 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 612 days as determined by the USPTO.

95. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 1012 days, which is the difference between the total period of USPTO delay (1624 days) and the period of applicant delay (612 days).

96. The Defendant’s imposition of only 343 days of patent term adjustment for the ’412 patent is arbitrary, capricious, an abuse of discretion, inconsistent with the language of 35 U.S.C. § 154 and related rules, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

PRAYER FOR RELIEF

97. The allegations of paragraphs 1-96 are incorporated in this prayer for relief as if fully set forth.

WHEREFORE, Alexion prays that the Court:

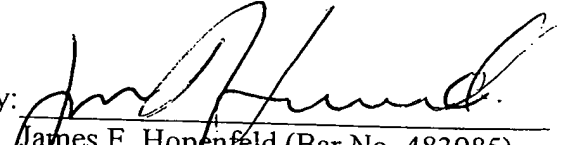
A. Issue an Order changing the period of patent term adjustment for the ’648 patent from 462 days to at least 758 days, and requiring Defendant to alter the term of the ’648 patent to reflect the 758-day patent term adjustment;

- B. Issue an Order changing the period of patent term adjustment for the '917 patent from 413 days to at least 654 days, and requiring Defendant to alter the term of the '917 patent to reflect the 654-day patent term adjustment;
- C. Issue an Order changing the period of patent term adjustment for the '594 patent from 512 days to at least 990 days, and requiring Defendant to alter the term of the '594 patent to reflect the 990-day patent term adjustment;
- D. Issue an Order changing the period of patent term adjustment for the '041 patent from 258 days to at least 306 days, and requiring Defendant to alter the term of the '041 patent to reflect the 306-day patent term adjustment;
- E. Issue an Order changing the period of patent term adjustment for the '111 patent from 549 days to at least 870 days, and requiring Defendant to alter the term of the '111 patent to reflect the 870-day patent term adjustment;
- F. Issue an Order changing the period of patent term adjustment for the '665 patent from 379 days to at least 812 days, and requiring Defendant to alter the term of the '665 patent to reflect the 812-day patent term adjustment;
- G. Issue an Order changing the period of patent term adjustment for the '412 patent from 343 days to at least 1012 days, and requiring Defendant to alter the term of the '412 patent to reflect the 1012-day patent term adjustment; and

H. Grant to Alexion such other and further relief as the nature of the case may admit or require and as this Court deems just and proper.

Respectfully submitted,

By:



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ALEXION PHARMACEUTICALS,
INC.

Dated: December 23, 2008